EPA/OCSPP Announcement On PFAS

Background Information

Per- and polyfluoroalkyl substances (PFAS) are a group of man-made chemicals that includes PFOA, PFOS, GenX, as well as many other chemicals which can be quite varied. PFAS have been manufactured and used in a variety of industries around the globe, including in the United States since the 1940s. There is evidence that exposure to some PFAS chemicals can lead to adverse environmental and human health effects. Even given all of the available information there is more to be done which is why the Office of Chemical Safety and Pollution Prevention (OCSPP) is announcing a new strategy that will better position the office to address the current and likely upcoming concerns related to PFAS chemicals.

There are many ongoing activities which have prompted the development of this strategy. Most notable is Administrator Regan's recent policy memo issued on PFAS which instructs EPA to build on the 2019 PFAS Action Plan. Additionally, external entities have also noted this need and their efforts have included submission of a TSCA Section 21 petition by multiple organizations in October 2020 noting PFAS contamination in the Cape Fear river, PFAS being identified in pesticide containers associated with mosquito control applications in 2 states to date, and NGO recommendations for updating the 2019 PFAS Action Plan.

OCSPP is currently engaged in numerous activities related to PFAS to move forward on this timely issue by using its TSCA authorities to collect additional information on PFAS. Examples include a Section 8a7 Rule which will be proposed soon that will capture manufacturing data such as production volumes, exposure information and health effects data. Additionally, lower thresholds for reporting and additional chemicals have been added to the Toxic Release Inventory. The laboratory at Fort Meade has also been involved in analytical methods development efforts along with testing pesticide containers that have been potentially contaminated with various PFAS.

But, OCSPP needs to go further to be responsive to the issues noted above and to Administrator Regan's call to move forward on the PFAS issue. There is a current clear need to provide consistency to these efforts OCSPP so to that end OCSPP has developed a PFAS Testing Strategy which will guide its efforts in this area. This testing strategy will serve as a guidance document as we move proceed with development of the data and tools necessary for credible risk assessments being as timely as possible and expeditiously using appropriate resources.

These efforts will clearly not be done in a void given the breadth of the PFAS issue not only within EPA but nationally and internationally as well. As such, OCSPP is committed to collaborating across EPA and with appropriate external partners including Federal government agencies and departments, state and local agencies, and the private sector. For example, OCSPP is already collaborating with EPA's Office of Research and Development (ORD) to ensure that the efforts of both organizations build upon each other given each have available data,

tools, and other key information. Such collaboration will also feed into the efforts of the recently established EPA Council on PFAS.

Testing Strategy

The proposed testing strategy has eight key elements which are designed to guide OCSPP through the identification, evaluation, and use of data related to PFAS to enhance the risk assessment approaches which will be used. The elements include:

- **Scoping** – will use pertinent lists of possible chemicals of concern to frame an initial master list of chemicals to focus upon
- **Data Inventory** – will compile applicable data across multiple sources, this may also involve consideration of CBI data
- **Categorization** – this effort will group chemicals into bins based on factors such as structure, mechanistic similarities, toxicokinetic similarities, p-chem properties, persistence, and bioaccumulation potential
- **Leverage Existing Tools/Programs** – this will ensure OCSPP collaborates across appropriate organizations to ensure completeness and consistency on the PFAS issue, it will also preserve resources
- **Select Index Chemicals** – due to the sheer numbers of chemicals and the anticipated similarities between chemicals in the same bins the use of the index chemical concept is proposed, criteria will be developed to appropriately identify and select such chemicals
- **Data Needs Identification** – the data for selected index chemicals will be examined and needs for additional information will be assessed, additionally data needs for other chemicals in a bin will be evaluated to appropriately link these to the bin-specific index chemical
- **Require Data Under Statutory Authority For Index Chemicals and Related Chemicals** – TSCA Section 4 Test Orders and the FIFRA Data Call Ins will be issued to responsible parties as applicable to obtain identified information, these orders will be strategically developed to avoid overlap with identified existing data
- **Complete Evaluation and Read Across** – data reviews and profiles will be developed for the index chemicals (e.g., hazard assessment), additionally read across to other chemicals in each bin will be completed

Already Ongoing Efforts Related To Initial Testing Strategy

OCSPP is already involved in activities related to the proposed testing strategy which are described here. OCSPP and ORD are collaborating on efforts to develop lists of chemicals of concern based on current activities. Data identification and curation efforts are also ongoing using OCSPP internal databases and with the ORD through its Comptox Dashboard.

OCSPP has "working definition" for PFAS which will be considered as well as other efforts focused on development of a unified definition. The choice of definition has implications with

regard to which chemicals are included or excluded in any regulatory effort. The naming and characterization approach initially proposed by Buck et al (2011) was revised to 53 structural categories. Further grouping considerations beyond structure may include mechanistic (mode of toxic action), toxicokinetic, and physical-chemical similarities as well as persistence and bioaccumulative potential. Other considerations will also include noted concerns (e.g., Cape Fear petition list), use patterns and resulting exposure concerns.

OCSPP has been collaborating with ORD on how to best utilize the in vitro toxicity and toxicokinetic testing on a subset PFAS that were selected to support category read-across approaches which has been conducted. This has included building a PFAS screening library and screening a subset of those chemistries. The types of studies have included in vitro, toxicokinetic, and clearance studies (e.g., hepatotoxicity, developmental toxicity, immunotoxicity, mitochondrial toxicity, developmental neurotoxicity, endocrine disruption, general toxicity, intrinsic hepatic clearance, plasma protein binding (PPB), and renal reuptake). In addition to the testing described above, ORD has completed extensive data gathering to identify available existing toxicity information on substances meeting the PFAS definition. A systematic review approach was used to identify studies in the public domain, and key words present in the abstracts of these studies were used to characterize the types of information contained within those studies. Evidence maps from this effort provide a quick overview of the [HYPERLINK "https://public.tableau.com/app/profile/literature.inventory/viz/PFAS-150EvidenceMapVisualizations/HumanStudies"] and[HYPERLINK "https://public.tableau.com/app/profile/literature.inventory/viz/PFAS-150EvidenceMapVisualizations/HumanStudies"].

OCSPP is also reviewing its internal data systems to identify studies submitted under the Toxic Substances Control Act (TSCA). Studies may be submitted under several parts of the regulation, including as part of a pre-manufacture notice (PMN) or low volume exemption (LVE). If a company (manufacturer, importer, processor or distributor) becomes aware of information which reasonably supports a conclusion that the subject chemical or mixture presents a substantial risk of injury to health or the environment, it is required under TSCA section 8(e) to inform the EPA and provide the information. For organizations and people not subject to reporting requirements but who desire to inform EPA of information on potential toxic substances, or when negative or equivocal toxicity data are developed, study information may be submitted under the "For Your Information" (FYI) classification.

Results from the data gathering effort will be analyzed with respect to the PFAS categories so that important endpoints necessary for assessing hazard are covered by at least one representative substance in each category. Endpoints of interest may be customized for each PFAS category but generally cover physical-chemistry and fate, human health hazard and environmental hazard disciplines. Endpoints derived from EPA or internationally harmonized test guidelines guide the information sought for risk assessments although all available information will be considered. In vitro results and model predictions will be analyzed with respect to concordance with standard guideline endpoints for chemicals where both data types exist. This analysis will inform the confidence on extrapolation of these alternative study types to substances without traditional endpoint data and will be used to support or refine PFAS categories. Data gaps identified for each of the categories will guide the research and testing needs of this PFAS testing strategy.

More Detailed Information Is Available

[HYPERLINK "https://www.epa.gov/pfas"]

[HYPERLINK "https://www.epa.gov/sites/production/files/2021-04/documents/per-and_polyfluoroalkyl_substances.memo_.signed.pdf"]

[HYPERLINK "https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/support-documents-pfas-testing-section-21-petition"]

[HYPERLINK "https://www.epa.gov/pesticides/pfas-packaging"]

[HYPERLINK "https://www.environmentalprotectionnetwork.org/wp-content/uploads/2021/04/EPN-PFAS-Action-Plan-Recommendations.pdf"]

[HYPERLINK "https://pubmed.ncbi.nlm.nih.gov/30632786/"]

[HYPERLINK "https://comptox.epa.gov/dashboard"]

OCSPP Testing Strategy Proposal - attached